



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

SAMSUNG MEDISON CO., LTD  
C/O MARK JOB  
1394 25TH STREET, NW  
BUFFALO MN 55313

December 9, 2014

Re: K143264  
Trade/Device Name: H60 V2.00 Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: November 12, 2014  
Received: November 13, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041

or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. In the background, there is a faint, large, light gray watermark of the letters "FDA".

for

Janine Morris

Director

Division of Radiological Health

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K143264

Device Name

H60 Diagnostic Ultrasound System

Indications for Use (Describe)

The H60 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: H60 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P	P	P	Note 1	Notes 2, 4, 7, 8, 9, 11, 12
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Note 2, 4, 5, 6, 7, 8, 9, 11
	Small Organ ( <i>See Note 5</i> )	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12
	Neonatal Cephalic	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Adult Cephalic	P	P	P	P	P	Note 1	Notes 4, 7
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Notes 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Notes 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CS1-4 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C2-8 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CF4-9 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Small Organ ( <i>See Note 5</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: ER4-9 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 8
	Abdominal ( <i>See Note 10</i> )							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 8, 12
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 8, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )	P	P	P		P	Note 1	Notes 2, 8, 12
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)



## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: EVN4-9 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 8
	Abdominal ( <i>See Note 10</i> )							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 8, 12
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 8, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )	P	P	P		P	Note 1	Notes 2, 8, 12
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L5-13 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )							
	Abdominal ( <i>See Note 10</i> )							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Small Organ ( <i>See Note 5</i> )	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: 3D2-6 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Note 2, 4, 7, 8, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: VE4-8 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Note 2, 4, 7, 8, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: 3D4-9 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 7, 8,
	Abdominal ( <i>See Note 10</i> )							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 12
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )	P	P	P		P	Note 1	Notes 2, 8, 12
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CF2-8 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LF5-13 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )							
	Abdominal ( <i>See Note 10</i> )							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Small Organ ( <i>See Note 5</i> )	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PE2-4 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )							
	Abdominal ( <i>See Note 10</i> )	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)



## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: SP3-8 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )							
	Abdominal ( <i>See Note 10</i> )	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW2.0 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )							
	Abdominal ( <i>See Note 10</i> )							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW4.0 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )							
	Abdominal ( <i>See Note 10</i> )							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric				P			
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA1-7AD for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT**

510(k) No.:

Device Name: CA2-8AD for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT**

510(k) No.:

Device Name: VR5-9 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-14AD for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )							
	Abdominal ( <i>See Note 10</i> )							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Intra-luminal							
	Other ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V5-9 for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Abdominal ( <i>See Note 10</i> )	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other ( <i>See Note 13</i> )	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)



## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CV1-8AD for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics ( <i>See Note 3</i> )	N	N	N		N	Note 1	Note 2, 4, 7, 8, 9, 11
	Abdominal ( <i>See Note 10</i> )	N	N	N		N	Note 1	Note 2, 7, 8, 9, 11
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) ( <i>See Note 13</i> )							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: DP2B for use with H60

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal ( <i>See Note 3</i> )							
	Abdominal							
	Intra-operative ( <i>See Note 6</i> )							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ ( <i>See Note 5</i> )							
	Neonatal Cephalic							
	Adult Cephalic				N			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				N			
	Cardiac Pediatric				N			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				N			
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

**1. Submitter's Information: 21 CFR 807.92(a)(1)**

SAMSUNG MEDISON CO., LTD.  
42, Teheran-ro 108-gil, Gangnam-gu,  
Seoul, Korea

**Contact Person:**

Kyeong-Mi, Park  
Regulatory Affairs Manager

Telephone: 82.2.2194.1373

Facsimile: 82.2.556.3974

**Data Prepared:** October 8, 2014

**2. Name of the device:**Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

H60 Diagnostic Ultrasound System

<u>Classification Names:</u>	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

**3. Identification of the predicate or legally marketed device:**

- UGEO H60 Diagnostic Ultrasound System (K132861)
- RS80A Diagnostic Ultrasound System (K141620)
- UGEO WS80A Diagnostic Ultrasound System (K133329)
- UGEO PT60A Diagnostic Ultrasound System (K142466)

#### **4. Device Description:**

The H60 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging (including Directional Power Doppler mode; S-Flow), PW Spectral Doppler mode, CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, Tissue Doppler Wave, 3D imaging mode (real time 4D imaging mode), Elastoscans Mode or as a combination of these modes. The H60 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The H60 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

#### **5. Intended Uses:**

The H60 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organs, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

#### **6. Technological Characteristics:**

The H60 is substantially equivalent with respect to safety, effectiveness, and functionality to the UGEO H60 Diagnostic Ultrasound System (K132861), RS80A Diagnostic Ultrasound System (K141620), UGEO WS80A Diagnostic Ultrasound System (K133329) and UGEO PT60A Diagnostic Ultrasound System (K142466).

All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

These are described in detail in the technological characteristics comparison table as below.

## &lt;Change list&gt;

	H60 (V2.00)	Comment																
Model Name	<ul style="list-style-type: none"><li>Change of model name in the V2.00</li></ul>																	
Clinical application	<ul style="list-style-type: none"><li>No addition</li></ul>	The clinical application was described in more detail.																
Operation of modes	<ul style="list-style-type: none"><li>No addition</li></ul>																	
Applied transducers	<ul style="list-style-type: none"><li>Addition of 7 transducers : CA1-7AD, CA2-8AD, VR5-9, LA3-14AD, V5-9, CV1-8AD and DP2B</li></ul>	<table><tr><td>Transducers</td><td>The previously cleared transducers</td></tr><tr><td>CA1-7AD</td><td>K141620</td></tr><tr><td>CA2-8AD</td><td>K132861 (CF2-8)</td></tr><tr><td>VR5-9</td><td>K133329</td></tr><tr><td>LA3-14AD</td><td>K141620 (L3-12A)</td></tr><tr><td>V5-9</td><td>K141620</td></tr><tr><td>CV1-8AD</td><td>None</td></tr><tr><td>DP2B</td><td>None</td></tr></table>	Transducers	The previously cleared transducers	CA1-7AD	K141620	CA2-8AD	K132861 (CF2-8)	VR5-9	K133329	LA3-14AD	K141620 (L3-12A)	V5-9	K141620	CV1-8AD	None	DP2B	None
Transducers	The previously cleared transducers																	
CA1-7AD	K141620																	
CA2-8AD	K132861 (CF2-8)																	
VR5-9	K133329																	
LA3-14AD	K141620 (L3-12A)																	
V5-9	K141620																	
CV1-8AD	None																	
DP2B	None																	
SW Features	<ul style="list-style-type: none"><li>Addition of S/W Features : (new) None (previously cleared) Panoramic, Elastoscan, XI STIC, Auto IMT+, Needle Mate</li><li>Change of S/W feature’s name : SCI→MultiVision, SDMR→ClearVision</li></ul>	<p>Description of S/W Features</p> <ul style="list-style-type: none"><li>Panoramic: It provides to a wider range of image views using a mosaic technique form continuous ultrasound images.</li><li>Elastoscan: This process converts the elastic modulus (ultrasound image data) of a target object obtained from continuous ultrasound images into an elastogram. A lesion's location can be estimated by using the differences in elastic modulus obtained from elastograms. It to determine the hardness or stiffness between healthy organs and lesions.</li><li>XI STIC: This view mode is enabled if 3D image acquisition is completed when MSV or Oblique View is selected in 3D StandBy. An image can be viewed in multiple slices.</li><li>Auto IMT+: It provides to calculate IMT (Intima-Media Thickness) and analyze measured values by One-step operation. (It is same with Auto IMT)</li><li>Needle Mate: It provides the Needle Mate function to display the Needle position more clearly in B Image by emphasizing the Needle image.</li></ul>																
HW Features	<ul style="list-style-type: none"><li>No Change</li></ul>																	

&lt;Technological Characteristics Comparison Table&gt;

Feature / Characteristics	The subject device	The predicate devices			
	H60	UGEO H60 (K132861)	RS80A (K141620)	UGEO WS80A (K133329)	UGEO PT60A (K142466)
Indication for Use					
- Fetal/Obstetrics	√	√	√	√	√
- Abdominal	√	√	√	√	√
- Gynecology	√	√	√	√	√
- Pediatric	√	√	√		
- Small Organ	√	√	√	√	√
- Neonatal Cephalic	√	√	√		
- Adult Cephalic	√	√	√		√
- Trans-rectal	√	√	√	√	√
- Trans-vaginal	√	√	√	√	√
- Musculo-skeletal (Conventional)	√	√	√	√	√
- Musculo-skeletal (Superficial)	√	√	√	√	√
- Urology	√	√	√	√	√
- Cardiac Adult	√	√	√		√
- Cardiac Pediatric	√	√	√		√
- Peripheral vessel	√	√	√	√	√
Scanhead Types					
- Linear Array	√	√	√	√	√
- Curved Linear Array	√	√	√	√	√
- Endocavity	√	√	√	√	√
- Phased Array	√	√	√		√
- Static Probes	√	√	√		
Scanhead Frequency					
1.0 ~ 20.0 MHz	√	√	√	√	√
Modes of Operation					
- B-mode	√	√	√	√	√
- M-mode	√	√	√	√	√
- Pulsed wave (PW) Doppler	√	√	√	√	√
- Continuous wave (CW) Doppler	√	√	√		
- Color Doppler	√	√	√	√	√
- Power Amplitude Doppler	√	√	√	√	√
- Tissue Harmonic Imaging	√	√	√	√	√
- 3D/4D imaging mode	√	√	√	√	
- Combined modes	√	√	√	√	√
Safety & EMC Compliance					
- IEC 60601-1					
- UL 60601-1	√	√	√	√	√
- CSA C22.2 No.601.1					
- IEC 60601-2-37	√	√	√	√	√
- IEC 60601-1-2	√	√	√	√	√

Feature / Characteristics	The subject device	The predicate devices			
	H60	UGEO H60 (K132861)	RS80A (K141620)	UGEO WS80A (K133329)	UGEO PT60A (K142466)
Acoustic Output Display Standard					
Track 3	√	√	√	√	√
Patient Contact Materials					
Tested to ISO 10993-1	√	√	√	√	√
Functionality					
- Quick Scan (Q Scan)	√	√	√	√	√
- Spatial Compound Imaging	√ <sup>1)</sup>	√	√	√	√
- SMDR (SMDR evo)	√ <sup>2)</sup>	√	√	√	√
- Auto IMT+ (Auto IMT)	√	√	√	√	√
- Elastoscan	√		√	√	
- Panoramic	√		√	√	
- 3D Imaging (Volume Data Acquisition)	√	√	√	√	
- 3D Imaging presentation 3D Cine/4D Cine	√	√	√	√	
- 3D Rendering MPR(Multi Planer Render)	√	√	√	√	
- 3D XI MSV(Multi Slice View) Oblique View	√	√	√	√	
- 3D MXI Volume Slice, Mirror View			√	√	
- XI Volume CT (Volume CT)			√	√	
- 3D MagiCut	√	√	√	√	
- Volume Calculation (VOCAL, XI VOCAL)	√	√	√	√	
- XI STIC	√		√	√	
- Volume NT/IT	√	√	√	√	
- e-Motion Marker	√	√			
- Needle Mate	√		√		√

1) The name of the feature is changed to MultiVison.

2) The name of the feature is changed to ClearVision

**7. A brief discussion of the bench and non-clinical tests conducted on the subject device**

The device has been evaluated for acoustic output, biocompatibility effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform to applicable medical device safety standards.

The H60 and its application comply with voluntary standards as below:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biocompatibility
- ISO14971, Application of risk management to medical devices

Summary of Clinical Tests:

Not applicable. The subject of this submission, H60, did not require clinical studies to support substantial equivalence.

**8. Conclusion**

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the H60 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

**END of 510(K) Summary**